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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,847	10/30/2003	Arkady Glukhovsky	P-5476-US	8263

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EXAMINER

SMITH, PHILIP ROBERT

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,847	GLUKHOVSKY ET AL.	
	Examiner	Art Unit	
	Philip R. Smith	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/30/03 & 8/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

[01] The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[02] Claims 1-18 & 20-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Denen et al. (5,400,267), patented 21 March 1995.

[03] With regard to claims 1-2, 10, 13-15, 17-18, 20, 27 & 29-30: Denen discloses an autonomous in-vivo device ("medical equipment 31," column 10/ lines 36-45) comprising an operation blocker and circuit (comprising "control module 36" & "non-volatile memory 30" for storing "utilization history," 10/46-57) to permanently prevent activation (11/22-27) of said device after a specified condition ("utilization limits," 11/9-12) is satisfied.

[04] With regard to claim 3: The operation blocker disclosed by Denen comprises a non-volatile memory configured for assuming a designated state ("utilization limits") upon said satisfaction of said specified condition.

[05] With regard to claims 4-5, 8, 21 & 33: Denen discloses an operation blocker responsive to the satisfaction of a specified condition, thus anticipating the claim. Elapsation of time may inherently be the specified condition. So long as no

structure which measures time is positively recited, no anticipatory structure is required. However, Denen does in fact disclose that specified condition may be any of those disclosed in 10/42-45: "a maximum procedure count, a maximum equipment actuation count, a maximum equipment actuation time and a maximum sterilization count." This necessitates a timer.

[06] With regard to claims 6 & 23: Denen discloses an operation blocker responsive to the satisfaction of a specified condition, thus anticipating the claim. A voltage level may inherently be the specified condition. So long as no structure which defines or senses voltage is positively recited, no anticipatory structure is required. However, Denen does in fact disclose that the specified condition may include "parametric data... for example, voltage limits, current limits, instrument impedance, voltage setpoints, current setpoints, voltage ranges, current ranges, and scale factors" (9/27-30).

[07] With regard to claim 7: Denen discloses an operation blocker responsive to the satisfaction of a specified condition, thus anticipating the claim. Receipt of a command may inherently be the specified condition. So long as no structure which commands is positively recited, no anticipatory structure is required. However, Denen does in fact disclose that satisfaction of the specified condition results in receipt of a command ("disabling message," 11/26).

[08] With regard to claims 9, 24 & 26: Denen discloses that the specified condition is satisfied by a sensor of said device detecting a pre-defined external environment ("input from actuator 37," 11/58-62).

- [09] With regard to claims 11, 22, & 31: Denen discloses an operation blocker responsive to the satisfaction of a specified condition. A counter exceeding a predefined number of captured images may inherently be the specified condition. So long as no structure which images is positively recited, no anticipatory structure is required; so long as no structure which counts is positively recited, no anticipatory structure is required.
- [10] With regard to claim 12: Denen discloses the recited operation blocker. Since no structural or functional relationship between the device comprising operation blocker and battery is claimed, Denen is anticipatory. "A battery," as claimed by Applicant, includes within its scope all batteries in existence previously or concurrently with the claimed device. Since Denen's invention may inherently coexist with a replaceable or removable battery, it anticipates the claim.
- [11] With regard to claim 25: Denen's invention inherently permits continued operation after the satisfaction of a predetermined condition, e.g. the activation of the device.
- [12] With regard to claim 28: Denen discloses a generic "limited use therapeutic device" (1/12-28), indicated broadly as "medical device 31." This is explicitly resolved to include "endoscopic devices" and "physiologic sensors." Endoscopic devices inherently include imaging among their operation.
- [13] With regard to claim 32: As noted above, Denen discloses an operation blocker responsive to the satisfaction of a specified condition. So long as no structure which senses an in-vivo environmental condition is positively recited, no

anticipatory structure is required.

Claim Rejections - 35 USC § 103

- [14] The text of those sections of Title 35, U.S. Code The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this

Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- [15] Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Denen in view of Kane et al. (6,204,746), patented 20 March 2001.
- [16] As shown above, Denen discloses a method for preventing reuse of an in-vivo device comprising activating a permanent operation blocker in said device upon satisfaction of a specified condition. Denen does not disclose that the activation of the operation blocker comprises melting of an insulation.
- [17] Kane discloses a mechanism which includes a "thin breachable or breakable membrane 38... preferably formed of... plastic... designed to melt or break" (2/49-54). At the time of the invention, it would have been obvious to a person of ordinary skill in the art that in reducing to practice the invention of Denen, the operation blocker may include the invention disclosed by Kane as a means of deactivating the device.

Conclusion

- [18] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Thorne (3,146,326) and Hogan (2,216,974) disclose activators which melt insulation. Uehara (5,609,561) discloses a switch for deactivating a CCD driver during sterilization. Enomoto (5,967,969) discloses an endoscope whose use is interrupted if overuse is calculated. Eto (6,436,032) and Shibata (2001/0041825) disclose endoscopes which are labeled unavailable based on calculated overuse. Meadows (6,516,227) discloses a therapeutic device which cuts off a battery whose voltage falls below a certain level. Kura (6,712,756) monitors endoscope usage and recommends maintenance. Gazdzinski (2002/0103417) discloses a capsule endoscope which deactivates based on reached memory (image data) limitations.
- [19] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached on 10:00-6:00.
- [20] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
- [21] Information regarding the status of an application may be obtained from the Patent

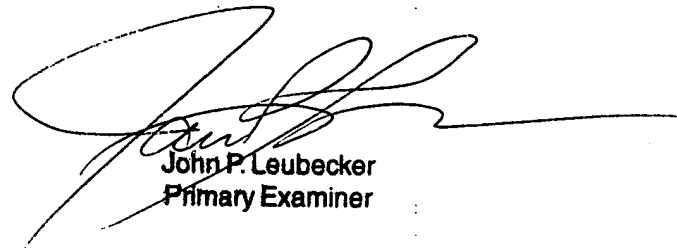
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Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prs



John P. Leubecker
Primary Examiner